IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BRIAN SPEAR, ET AL.	:	
	:	
v.	:	**CIVIL ACTION NO. 22-876**
	:	
ATRIUM MEDICAL CORP., ET AL.	:	

McHUGH, J. **August 12, 2022**

MEMORANDUM

Plaintiffs Brian and Amanda Spear bring this product liability action against Defendants Atrium Medical Corp., Maquet Cardiovascular US Sales LLC, and their parent company Getinge AB, alleging defects in ProLoop, a synthetic mesh medical device used for hernia repair. Defendants Atrium Medical and Maquet Cardiovascular (the "Domestic Defendants") have moved to dismiss the Complaint against them, principally asserting that strict liability is not available for product liability claims related to medical devices following the Pennsylvania Supreme Court's adoption of comment k to Restatement (Second) of Torts § 402A in *Hahn v. Richter*, 673 A. 2d 888, 891 (1996). Defendant Getinge AB, the parent, moves to dismiss for lack of personal jurisdiction, contending that its mere ownership of the offending manufacturers does not create sufficient contacts to vest this Court with jurisdiction. It also moves to dismiss for the reasons identified by its subsidiaries and because the Complaint does not allege facts that support liability against Getinge. For the reasons that follow, both motions will be granted in part and denied in part.

I. The Domestic Defendants' Motion to Dismiss under Rule 12(b)(6)

A. Standard of Review

The motion to dismiss of Atrium and Maquet is governed by Fed. R. Civ. P. 12(b)(6), as set forth in *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009).

B. Relevant Facts

The ProLoop device was originally implanted in Plaintiff Brian Spear during hernia surgery in January 2015. This action was brought in March 2022. Plaintiffs claim that Defendants marketed and sold the device despite knowing that the design, especially the material out of which it's constructed, presented serious risks to consumers. Plaintiffs bring their claim under several theories of liability including strict liability for defect in design (Count I), strict liability for failure to warn (Count II), negligence (Count III), breach of implied warranty (Count IV), breach of express warranty (Count V), and negligent misrepresentation (Count VI). They seek both compensatory and punitive damages.

C. Discussion

1. Strict Liability for Design Defect (Count I)

The central issue in the Domestic Defendants' motion to dismiss is whether Pennsylvania law *per se* excludes medical devices from strict liability. Courts in the Eastern District of Pennsylvania have come down on both sides of this issue, with a majority holding that medical devices cannot be subject to strict liability.[1] This ambiguous state of affairs derives from *Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996), a Pennsylvania Supreme Court decision that adopted comment k to Restatement (Second) of Torts § 402A, holding that prescription drugs were "unavoidably unsafe products" for which strict liability was inappropriate. In assessing whether *Hahn* should also apply to medical devices, courts in this district have looked to two distinct lines

[1] For the majority view, see *Bostic v. Ethicon Inc.*, 2022 WL 952129, at *9 (E.D. Pa. Mar. 29, 2022) (Padova, J.); *Brown v. C.R. Bard, Inc.*, 2022 WL 420914, at *4 (E.D. Pa. Feb. 11, 2022) (Leeson, J.); *Lopez v. Ethicon Inc.*, 2020 WL 5569770, at *5 (E.D. Pa. Sept. 17, 2020) (Quiñones Alejandro, J.); *Keen v. C.R. Bard, Inc.*, 480 F. Supp. 3d 624, 637 (E.D. Pa. 2020) (Pratter, J.); *Kohn v. Ethicon, Inc.*, 2020 WL 733126, at *4-5 (E.D. Pa. Feb. 13, 2020) (Tucker, J.).

For the minority view, see *Gross v. Coloplast Corp.*, 434 F. Supp. 3d 245 (E.D. Pa. 2020) (Baylson, J.); *Ebert v. C.R. Bard, Inc.*, 459 F. Supp. 3d 637 (E.D. Pa. 2020) (Pappert, J.).

of cases from Pennsylvania appellate courts. Courts that have extended the comment k "unavoidably unsafe" designation to medical devices have followed *Creazzo v. Medtronic,* 903 A.2d 24, 31 (Pa. Super. Ct. 2006), a Pennsylvania Superior Court case that expressly applied the logic of *Hahn* to medical devices. Courts that have not barred strict liability have noted that *Creazzo* was argued by *pro se* plaintiffs and therefore unpersuasive as "indicia of how the Pennsylvania Supreme Court might decide the issue." *Mazur v. Merck & Co.*, 964 F.2d 1348, 1353 (3d Cir. 1992) (cleaned up). These courts have instead given more consideration to decisions issued by the Pennsylvania Supreme Court that suggest *Hahn*'s reach may be limited. First, in *Lance v. Wyeth*, 85 A.3d 434, 452 n.21 (Pa. 2014), the Court specifically cautioned against unwarranted extensions of *Hahn*. Then, in *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 396 (Pa. 2014), addressing strict liability generally, the Supreme Court warned against categorical exemptions from strict liability, endorsing fact-specific determinations instead. Historically, the law of product liability in Pennsylvania has been strongly protective of consumers. Given these decisions, there is little to support a prediction that the Pennsylvania Supreme Court would expand comment k to medical devices as a categorical exemption from strict liability.

Conceptually, the crux of the issue is whether the rationale supporting the application of comment k to drugs necessarily carries through to devices. It is not intuitively clear that it does. As to drugs, the premise is that they are intrinsically dangerous—that some risk necessarily accompanies their introduction into the human body. In large part, that is because drugs are comprised of biologics meant to interact with and have an effect upon human tissue. The same agent that is intended to attack disease can also attack healthy tissue. In the case of antibiotics, the root meaning of the word—"against life"—describes the risk. Given the complex diversity of the human species, different patients will respond in different ways, often for reasons that remain

opaque. Patients who outwardly appear the same may have subtle genetic or other differences that cue radically different responses. Within medicine, "idiosyncratic" drug reactions constitute their own field of study.[2] In the case of drugs, comment k recognizes that, as a matter of social utility, the suffering caused by certain conditions is such that patients are willing to take the risk of known and serious side effects. A recent example of this is the medication alosetron, marketed as Lotronex. FDA regulators pulled it from the market following a series of deaths, but in response to strong patient demand, later allowed its distribution with enhanced warnings.[3]

In contrast, medical devices, at least before implantation, are inert. They may not remain so, and their insertion may trigger a systemic response from the patient's body,[4] but their physical characteristics are significantly different from medications. If, with proper choice of materials and proper methods of fabrication, an implant can be supplied that is not inherently dangerous, then the rationale behind comment k does not readily apply. I am therefore persuaded that categorical application of comment k to devices is not consistent with Pennsylvania law, with the result that Plaintiffs' strict liability claim survives pending further development of the record.

2. Liability for Failure to Warn (Count II)

Defendants challenge Plaintiffs' failure to warn claim on two grounds. First, they summarily rely on *Hahn,* arguing that "*Hahn*'s holding bars strict liability claims in both design

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[2] Jack Uetrecht, *Mechanistic Studies of Idiosyncratic DILI: Clinical Implications*, Frontiers in Pharmacology 10:837 (2019).

[3] Ray Moynihan, *Alosetron: a case study in regulatory capture, or a victory for patients' rights?* BMJ 325(7364):592-5 (2002); Viola Andresen & Stephan Hollerbach, *Reassessing the benefits and risks of alosetron: what is its place in the treatment of irritable bowel syndrome?* Drug Safety 27(5):283-92 (2004); Denise Grady, *F.D.A. Pulls a Drug, And Patients Despair*, N.Y. Times, Jan. 30, 2001, at sec. F, col. 4, p. 1.

[4] *See, e.g.*, Esthela Loyo, Luis J. Jara, Persio David Lopez, & Ana Carolina Puig, *Autoimmunity in connection with a metal implant: a case of autoimmune/autoinflammatory syndrome induced by adjuvants*. Auto Immunity Highlights 4(1):33-8 (2012).

defect and failure to warn cases." Defs. Br. at 3 (citing *Crockett v. Luitpold Pharm., Inc.*, 2020 WL 433367, at *5 (E.D. Pa. Jan. 28, 2020)). Because I have concluded that comment k does not provide a categorical bar to strict liability in design defect claims related to medical devices, I likewise conclude that there is no such categorical bar of failure to warn claims.

Second, Defendants object to the lack of specificity in the Complaint regarding any alleged defective warnings, contending that Plaintiffs bear a burden at pleading to "specify what information was missing from Defendants' warnings" so as to "address the precise injury posed by the use of the device." Defs. Br. at 10.[5] Plaintiffs have identified serious risks associated with the device, Compl. ¶ 3, alleged that Defendants knew or should have known about such risks, Compl. ¶¶ 19, 45-47, and have pleaded that "Defendants misrepresented and concealed from … Plaintiff's physicians … the serious risks, dangers and defects enumerated in this Complaint," Compl. ¶¶ 37, 53. I am not persuaded that a plaintiff in a medical device case bears a burden of pleading in complete detail at the outset of the case the specific content of the warning necessary to offset the risks posed by use of the device. In the first instance, in the absence of discovery, a plaintiff does not yet know if there were risks known to the supplier that were not disclosed or may have been minimized during development or testing of the device. In that regard, the Pennsylvania Superior Court has recognized in the context of medications that "[g]enerally, expert medical testimony is required to determine whether the drug manufacturer's warning to the medical community is adequate because prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect." *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1154 (Pa.

[5] Defendants also argue that "[t]o the extent Plaintiffs' failure to warn claims are premised on an alleged failure to warn Mr. Spears directly …, they should be dismissed" due to the application of the learned intermediary doctrine, such that a manufacturer of a medical device discharges their duty to warn by providing an adequate warning to the physician. Defs. Br. at 10. Plaintiffs appear to concede this, as they must under current Pennsylvania law. *Taurino v. Ellen*, 579 A.2d 925, 927 (Pa. Super. 1990).

Super. 1996), *appeal denied,* 684 A.2d 557 (Pa. 1996). A requirement that the plaintiff must tender expert reports at the outset of a case is onerous and unrealistic. In practical terms, the testimony of treating physicians will be necessary, *Simon v. Wyeth Pharms., Inc.*, 989 A.2d 356, 375 (Pa. Super. 2009), and for a treating physician to opine about what would have been relevant to their decision-making also requires the development of a factual record. This portion of the motion will therefore be denied. *See Runner v. C.R. Bard,* 108 F. Supp. 3d 261, 271 (E.D. Pa. 2015).

3. Liability under a Negligence Theory (Count III)

As a general matter, the Pennsylvania Supreme Court has recognized the availability of a negligence action for design defect claims through its adoption § 398 of the Second Restatement of Torts. *Lance v. Wyeth*, 85 A.3d 434, 445 n.13 (Pa. 2014) (citing *Foley v. The Pittsburgh-Des Moines Co.,* 68 A.2d 517, 531 (Pa. 1949)). More recently, it has endorsed claims alleging negligent design in the context of pharmaceutical products. *Id.* at 458. There is broad language in *Lance* as to the scope of duty owed by suppliers of medical products: "[T]he law of negligence establishes a duty, on the part of manufacturers, which can be viewed on a continuum from the requirements of: a warning of dangers, through a stronger warning if justified by the known risks, through non-marketing or discontinuance of marketing when it becomes or should become known that the product should not be used in light of its relative risks." *Id.* at 459–60. Some decisions in this district deem this statement to be *dicta,* and interpret *Lance* as limiting negligent design claims involving medical products solely to the theory that the product was too dangerous to market. *See, e.g.*, *Ebert,* 459 F. Supp. 3d at 644. Other decisions have concluded that a plaintiff can assert a broader theory of liability to include the claim that sound design requires the product to be accompanied by warnings. *See, e.g.*, *Crockett,* 2020 WL 433367, at *11. I am persuaded that the broader view finds more support in Pennsylvania law. The Pennsylvania Supreme Court

recognized liability for negligent failure to warn long before adoption of the Second Restatement. *See, e.g., Maize v. Atlantic Refining Co*., 41 A.2d 850, 853 (Pa. 1945); *Hopkins v. E.I. Du Pont De Nemours & Co.,* 199 F.2d 930, 932-33 (3d Cir. 1952). If the Supreme Court meant to limit such theories in the context of medical devices, I would expect it to do so explicitly. Moreover, its recognition of the theory that some products may be too dangerous to market represents an evolution in Pennsylvania law, as previously such a theory of recovery had been rejected. *See Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp*., 596 A.2d 845, 849 (Pa. Super. 1991); *Hite v. R.J. Reynolds Tobacco Co.,* 578 A.2d 417, 420-21 (Pa. Super. 1990).

Regardless of the scope of the claim, *Lance* clearly endorsed the proposition that liability attaches where the company "knows or should know [the drug] is so dangerous that it should not be taken by anyone," and district courts in this circuit have found this duty of care to be equally applicable to medical device claims. *See Ebert*, 459 F.Supp.3d at 644; *Stevens v. C. R. Bard, Inc.*, No. 17CV1388, 2018 WL 692097, at *3 (W.D. Pa. Feb. 2, 2018); *Kramme v. Zimmer, Inc.*, No. 3:11-CV-00916, 2015 WL 4509021, at *6 (M.D. Pa. July 24, 2015).

Defendants appear to accept that such a duty of care exists but contend that it is "unclear from the Complaint whether Plaintiffs intend to assert such a categorical theory of defect." Dom. Defs. Br. at 7 n.2, ECF 9-1. I find this objection make-weight, especially where failure to warn remains in the case regardless.[6] Defendants' more substantive argument is that "Plaintiffs's negligent design defect claim should be dismissed for failure to allege a feasible alternative design." *Id.* at 7. I disagree.

[6] With respect to whether Defendants have notice of a "categorical theory" of design defect, I note that within their expressly stated claim for negligence, Plaintiffs plead that "[d]espite the fact that Defendants knew or should have known that ProLoop polypropylene mesh caused unreasonable and dangerous risks and complications, and failed to warn of those risks and complications, Defendants continued to market ProLoop polypropylene mesh to consumers including Plaintiff." Compl. ¶ 64.

To the extent that Plaintiffs proceed under the theory that the product was too dangerous to market, then by definition no alternative design is necessary. Defendants are correct that if Plaintiffs argue the product could have been marketed safely with better design, they will ultimately bear the burden of proving a feasible alternative design. *Habecker v. Clark Equip. Co.*, 942 F.2d 210, 215 (3d Cir. 1991).[7] But I decline to follow *McGrain v. C.R. Bard, Inc.,* 551 F. Supp. 3d 529, 541-42 (E.D. Pa. 2021), as I do not accept that a plaintiff bears the burden of specifically pleading such a design as the outset.[8] And even if one assumes that a plaintiff must plead an alternative design in detail, I conclude that the Complaint here does so implicitly in Paragraphs 32 and 33, where it identifies specific design choices giving rise to the risk.[9]

4. Breach of Implied Warranty (Counts IV)

Defendants also argue that the implied warranty claim is untimely because the statute of limitations is four years and begins to run upon product delivery. This is an accurate statement of Pennsylvania law, *Nationwide Insurance v. General Motors Corp.,* 625 A.2d 1172 (Pa. 1993), and intermediate appellate courts have explicitly applied the rule to medical products. *Connaught Laboratories v. Lewis,* 557 A.2d 40, 44 (Pa. Cmwlth. 1989). Plaintiffs do not respond in their brief and I take them to have conceded the point. *See Dille v. Geer*, No. CV 20-924, 2020 WL 7624835, at *19 (E.D. Pa. Dec. 22, 2020). This claim will therefore be dismissed with prejudice.

[7] There is also language in *Lance* that could be read as generally calling into question the need to prove an alternative design in a product liability case. 85 A.3d at 459 n.36. Aside from it being *dicta*, I think it is best understood as related to the Court's approval of a theory not previously recognized by Pennsylvania law: that some products are too dangerous to market.

[8] I note as well that the line of Third Circuit precedent on which Defendants rely for this pleading requirement is limited to "crashworthiness" in vehicle design and does not apply more generally to all design defect claims.

[9] Defendants also assert that Plaintiffs have not adequately alleged a manufacturing defect. Plaintiffs concede that no formal claim has been pleaded, though argue that if it were, the Complaint alleges predicate facts to support it. Pltfs' Br. at 13. The issue is therefore not joined before me.

5. Breach of Express Warranty (Count V)

Under Pennsylvania law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." 13 Pa.C.S.A. § 2313. Because express warranties are specifically negotiated, "to create an express warranty, the seller must expressly communicate the terms of the warranty to the buyer in such a manner that the buyer understands those terms and accepts them." *Goodman v. PPG Indus., Inc.,* 849 A.2d 1239, 1243 (Pa. Super. 2004), *aff'd,* 885 A.2d 982 (Pa. 2005). Defendants argue that Plaintiffs' claims are inadequately pleaded because they fail to identify specific statements by the Defendants that represent the warranty. Defs' Br. at 13-14. I agree that Plaintiffs have pleaded nothing beyond general representations by Defendants in their marketing materials about the safety of the product. Defendants further contend that even if a warranty were identified, Plaintiffs have not met their obligation to notify Defendants prior to filing suit under 13 Pa.C.S.A. § 2607(c)(1). Once again, Plaintiffs fail to respond in their brief, so I likewise deem them to have conceded this point. This claim will therefore be dismissed with prejudice.

6. Negligent Misrepresentation (Count VI)

Plaintiffs' negligent misrepresentation claim derives from the same predicate facts as Plaintiffs' failure to warn claims. But as to this claim, Defendants argue that the Rule 9(b) pleading standard applies. I have previously noted that "[w]hether Rule 9(b) applies to negligent misrepresentation is disputed." *Vullings v. Bryant Heating & Cooling Sys.*, No. CV 18-3317, 2019 WL 687881, at *6 (E.D. Pa. Feb. 19, 2019) (citing *Schmidt v. Ford Motor Co.*, 972 F. Supp. 2d 712, 720 n.3 (E.D. Pa. Sept. 20, 2013)). But even where Rule 9(b) isn't formally applied, courts in this district have generally required negligent misrepresentation claims to be pleaded with a "degree of specificity." *See, e.g.*, *Brandow Chrysler Jeep Co. v. DataScan Techs.*, 511 F. Supp.

2d 529, 537 (E.D. Pa. 2007); *In re Am. Invs. Life Ins. Co. Annuity Mktg. & Sales Pracs. Litig.*, No. CIV.A. 04-2535, 2007 WL 2541216, at *31 (E.D. Pa. Aug. 29, 2007); *Floyd v. Brown & Williamson Tobacco Corp.,* 159 F.Supp.2d 823, 834 (E.D. Pa. 2001). Although Plaintiffs have provided sufficient detail regarding Defendants' knowledge of the risks, the Complaint provides only cursory information about representations in marketing materials. *See* Compl. ¶¶ 37, 77, 78. This claim will therefore be dismissed, but with leave to amend.

II. Defendant Getinge AB's Motion to Dismiss under Rule 12(b)(2)

Defendant Getinge AB's motion to dismiss for lack of personal jurisdiction is governed by Fed. R. Civ. P. 12(b)(2). After a defendant has raised such a challenge to personal jurisdiction, the burden shifts to the plaintiff to establish the court's jurisdiction over that defendant. *Miller Yacht Sales, Inc. v. Smith*, 384 F.3d 93, 97 (3d Cir. 2004).

On the record as it stands, Plaintiffs have not established a *prima facie* case of jurisdiction. They have, however, made enough of a showing to warrant discovery on jurisdiction. *Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446 (3d Cir. 2003) ("[C]ourts are to assist the plaintiff by allowing jurisdictional discovery unless the plaintiff's claim is 'clearly frivolous.'"). Plaintiffs are granted seventy-five (75) days within which to conduct such discovery.

III. Conclusion

Wherefore Defendants' motions to dismiss shall be granted in part and denied in part. Plaintiffs will be granted seventy-five (75) days to conduct jurisdictional discovery against Defendant Getinge AB. In the meantime, the parties shall commence merits discovery as to Atrium and Maquet, and they shall meet and confer for the purpose of proposing a Case Management Order. An appropriate order follows.

/s/ Gerald Austin McHugh
United States District Judge